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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,501	12/11/2003	Alessandra d'Azzo	SJ-01-0020A	9213

28258 7590 08/24/2006

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EXAMINER	
FRONDA, CHRISTIAN L	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/733,501	D'AZZO ET AL.	
	Examiner	Art Unit	
	Christian L. Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,21 and 22* is/are pending in the application.

4a) Of the above claim(s) *21 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☒ Claim(s) *2 and 3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/03, 7/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' election with traverse of the disease sialidosis and the corresponding enzyme α-α-neuraminidase in the reply filed on 07/11/2006 is acknowledged. The traversal is on the grounds that the methods are generic to the production and use of enzymes to treat lysosomal storage disorders and that a separate search of each disease-enzyme combination is unwarranted. This is not found persuasive because each of the diseases and enzymes or proteins are patentably distinct and independent and each disease has a different etiology. A search of all the diseases and enzymes in the patent literature and the non-patent literature cannot be made without serious burden because they require separate searches that have different limits, boundaries, scope, and subject matter. Accordingly, restriction for examination purposes is proper.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-6, sialidosis, and α-α-neuraminidase are under consideration in this Office Action. Claims 21 and 22 and the non-elected diseases and enzymes recited in claims 2 and 3, respectively, are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

4. Claims 2 and 3 are objected to because they recited non-elected enzymes and diseases. Applicants are required to amend the claims to recite the elected disease sialidosis and the corresponding enzyme α-α-neuraminidase.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to a genus of any protein of any structure and function or any active fragment thereof to be used in a composition for treating any lysosomal storage disorder including sialidosis wherein the claimed polypeptide is produced in insect cells. The specification, however, only provides a description of α-neuraminidase and protective protein/cathepsin A (PPCA) in a composition for treating PPCA deficient mice. There is no disclosure of any particular structure to function/activity relationship in the single PPCA to any other protein of any structure and function for treating any lysosomal storage disorder. The specification fails to provide a written description of any protein of any structure and function or any active fragment thereof of any structure and function to be used in a composition for treating any lysosomal storage disorder.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definitions, such as the structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v, Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), quoting *Fiers v. Revel,* 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe the genus of genetic materials, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g. structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these. Therefore, the instant claims are not adequately described.

Thus, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

7. Claim 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or

unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass any method for treating any lysosomal storage using any protein of any structure and function or any active fragment. The specification provides guidance and examples for injecting a baculovirus expressed and purified α-neuraminidase and PPCA into PPCA deficient mice resulting in increased activities of cathepsin A and α-neuraminidase. While molecular biological techniques and genetic manipulation techniques are known in the prior art and the skill of the artisan are well developed, knowledge regarding whether any protein of any structure and function or any active fragment can be used to treat any patient having any lysosomal storage disorder including sialidosis without harming the patient is lacking. Furthermore, knowledge regarding whether any baculovirus expressed and purified α-neuraminidase used to treat PPCA deficient mice can be used to treat any patient having sialidosis without harming the patient is lacking. Thus, searching for any protein or active fragment thereof of any structure and function or any baculovirus expressed and purified α-neuraminidase used to treat PPCA deficient mice which can be used to treat any patient having any lysosomal storage disorder without harming the patient is well outside the realm of routine experimentation and predictability in the art of success in determining whether the patient can be treated without any harm is extremely low.

The amount of experimentation to search for any protein or active fragment thereof of any structure and function which can be used to treat any patient having any lysosomal storage disorder including sialidosis without harming the patient is enormous and entails searching for any protein of any structure and function and determining whether any pharmaceutical composition comprising the protein or baculovirus expressed and purified α-neuraminidase would be useful in treating the patient having any lysosomal storage disorder including sialidosis without harming the patient.

Since such experimentation is not routine in the art where the expectation of obtaining any pharmaceutical composition comprising any protein or active fragment thereof of any structure and function which can be used to treat any patient having any lysosomal storage disorder including sialidosis is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the a specific composition which is effective in treating a patient having any lysosomal storage disorder including sialidosis. Without such guidance, the experimentation left to those skilled in the art is undue.

Conclusion

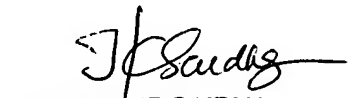
8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner

should be directed to Christian L. Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday- Friday from 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N. Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CLF



TEKCHAND SAIDHA
PRIMARY EXAMINER